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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,701	11/18/2003	Scott P. Fulton	GTC-206	5425

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,701	FULTON ET AL.	
	Examiner	Art Unit	
	Tiffany M. Gough	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method, as disclosed, in claim 1 and therefore the dependent claims , is confusing in that the method comprises the (a) blending of water in a controlled manner and the (b) buffering of acids and bases in a solution at a controlled ratio. However, the method does not disclose that steps (a) and (b) are being practiced together, therefore it is interpreted that the (a) and (b) are being practiced separately and not related. Further, the use of the terms "constitutive acids and bases" in claim 1 is unclear. As defined in the Webster's dictionary, constitutive means to make up; form. It is not clear as to what constitutive acids and bases are in regards to applicant's invention. Also the use of the terms "controlled manner" and "at a controlled ratio" do not distinctly claim how these steps are controlled. One skilled in the art would believe that the use of a stir bar in a beaker of water is a method of blending in a controlled manner or even further stirring by hand, and also that anytime you are buffering a solution with acids or bases to achieve a desired pH that one would control and therefore be knowledgeable of the amount of acids and bases or other required ingredients necessary to achieve such a desired pH.

Claim 4 recites the limitation "said biopharmaceutical" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not disclose a biopharmaceutical.

Further, there does not appear to be a relationship between the methods in claim 5 and 6 nor does it appear that claim 6 is further limiting the method of producing a buffered solution as claimed in claim 5. Claim 5 is drawn to a method of producing a buffer whereas claim 6 appears to be drawn to a completely different method, such as purifying a protein, human serum albumin, from a feedstream ,i.e. transgenic milk. It appears as if the claims are actually drawn to two different methods/inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Holum et al, (Laboratory Manual for Fundamentals of General, Organic and Biological Chemistry, 4th ed.,1990)

Applicant claims a method of producing pH buffered solutions comprising the blending of water and buffering acids and bases and other required ingredients in solution at a controlled manner and the buffering of acids and bases in a solution which

is done continuously. The buffered solutions are intended to be used in the processing of a biopharmaceutical such as human serum albumin.

Holum et al teach a method of producing a buffer using acids and bases to obtain a specific pH by adding acids and bases to water,mixing and recording the pH (see pg. 207-208).

Therefore the reference anticipates the claimed subject matter.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Voet et al (Biochemistry, 1990).

Applicant claims a method of producing pH buffered solutions comprising the blending of water and buffering acids and bases and other required ingredients in solution at a controlled manner and the buffering of acids and bases in a solution. The buffers produced are used for processing a biopharmaceutical and are produced continuously.

Voet et al teach buffer solutions, calculating a desired pH using the Henderson-Hasselbalch equation, the buffering effects of acids and bases based on the nature of acid-base reactions, and production of buffers by adding acid and/or base to water (see p.35-38). They further disclose (see Table 2-3) common acids, bases and buffers used as biochemical buffers in the laboratory. Further, they disclose the addition of an acid to water to obtain a desired pH and specifically show points at which a solution can function effectively as a buffer (see Fig. 2-9)

Although the reference only briefly teaches a method of producing a buffer, one of ordinary skill in the art would know how to prepare a buffer from mixing water either by hand or with a stir bar and how to buffer a solution by adding acids and/or bases to the solution to obtain a desired pH. In support, Wikipedia encyclopedia (http://en.wikipedia.org/wiki/Buffer_solution). Wikipedia provides a complete teaching of buffer solutions, calculating a desired pH using the Henderson-Hasselbalch equation, the buffering effects of acids and bases, tips on preparing an ideal buffer, i.e, one with a desired pH, common buffers used in Biology, such as TAPS, TRIS, HEPES, MOPS, MES etc. all commonly used buffers in biological sciences. Wikipedia also teaches how to prepare buffer solutions comprising the steps of mixing acids and bases and water to achieve specific pH's.

Therefore the reference anticipates the claimed subject matter.

Claims 1-5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Liebrecht et al (US 5,641,531, 1997).

Applicant claims a method of producing pH buffered solutions or formulations comprising steps of blending water and buffering acids and bases in solution along with any additional ingredients continuously. The buffer solutions are intended to be used for the processing of a biopharmaceutical, specifically human serum albumin.

Liebrecht et al teach the production of a formulation, which comprises the blending of water with other necessary ingredients and adjusting the pH of such

formulation with an acid to obtain a desired pH (see columns 2, lines 44-56, columns 3-4 lines 65-4).

Thus, the reference anticipates the claimed subject matter.

Claims 1-5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Moran (US 4,555,348, 1985)

Applicant claims a method of producing pH buffered solutions or formulations comprising steps of blending water and buffering acids and bases in solution along with any additional ingredients continuously. The buffer solutions are intended to be used for the processing of a biopharmaceutical, specifically human serum albumin.

Moran teaches the production of low and high pH buffered solutions comprising mixing water and acids and/or bases and additional ingredients to achieve a solution with a desired pH (see abstract, summary of invention and column 4, lines 35-65).

Thus, the reference anticipates the claimed subject matter.

Claims 1-5,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Illum (US 5,725,871, 1998).

Applicant claims a method of producing pH buffered solutions or formulations comprising steps of blending water and buffering acids and bases in solution along with any additional ingredients continuously. The buffer solutions are intended to be used for the processing of a biopharmaceutical, specifically human serum albumin.

Illum teaches the preparation of buffered solutions comprising mixing sodium phosphate and and water to obtain the desired pH. Insulin solutions were then prepared in the phosphate buffer (see column 6, lines 30-39).

Thus, the reference anticipates the claimed subject matter.

With respect to the USC 102 rejections above, it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

The claims,6-9, as disclosed in the instant application are so unclear and confusing (as discussed in the above 112 second rejections) that it is nearly impossible to properly determine the scope of the claims. However, for purposes of examination, they have been interpreted as a method for producing buffers, which are intended to be used for the processing of a biopharmaceutical, specifically human serum albumin (hSA) and a process for purifying/isolating human serum albumin using simulated moving bed

chromatography with the use of buffers. Applicant does not appear to be further limiting the method of buffer production between claims 5 and 6 and do not further incorporate the method of producing the buffers into the hSA production process.

Claims 1,4-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Fulton (US2003/0036637, filed June13,2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fulton teaches the processing of a feedstream, specifically, transgenic milk and/or transgenic cell cultures by applying the samples to an affinity column to obtain human serum albumin. Fulton also suggests using continuous chromatography, specifically simulated moving bed chromatography (see p.5, section 0056) to purify hSA from a transgenic source.

Fulton further discloses the necessary use of buffers at specific pH's throughout the purification process and also discloses a need to treat the transgenic milk with an acid, which in turn lowers pH and removes the casein present in the milk. Although Fulton does not specifically teach the a method of producing a buffer, a method of buffering a solution, i.e. milk with an acid, hSA with an acid or base (0053) , salt, wash

and elution buffers are adjusted by adding acid and/or salt (0051 and 0053), is taught and those buffers are further used in the hSA production process.

Therefore, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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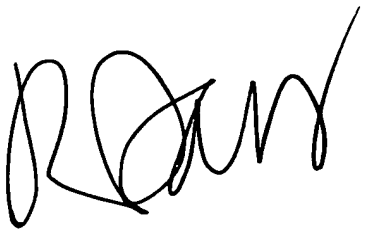

RUTH A. DAVIS
PATENT EXAMINER